

Attorney Docket No.: 1464-PCT-US-00

In re Application of Henry Daniel et al.

Serial No.: 09/807,723

Filed: April 18, 2001

For: GENETIC ENGINEERING OF PLANT CELLS TO PROVIDE ENHANCED
EXPRESSION OF MULTIPLE FOREIGN GENES IN TRANSGENIC PLASTIDS
UTILITIZING A SINGLE TRANSFORMATION EVENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Amendment in the above-identified application.

- Small entity status of this application under 37 CFR §1.9 and §1.27 has been established by a verified statement previously submitted.
- A verified statement to establish small entity status under 37 CFR §1.9 and §1.27 is enclosed.
- X No additional fee is required.

The fee has been calculated as shown below:

(Col. 1) (Col. 2) (Col. 3)

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PRE- VIOUSLY PAID FOR	PRESENT EXTRA
TOTAL	* 88	-	** 91=	
INDEP.	* 2	-	** 2=	
___ First presentation of multiple dependent claim				

SMALL ENTITY

RATE	ADD'L FEE
x 9=	\$
x42=	\$
+140=	\$

OR

OTHER THAN
SMALL ENTITY

RATE	ADD'L FEE
x18=	\$
x84=	\$
+280=	\$

TOTAL ADDITIONAL FEE \$0 OR \$_____

- * If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
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x Any filing fees under 37 CFR §1.16 for the presentation of extra claims.

x Any patent application processing fees under 37 CFR §1.17 with the exception of the Issue Fee which we intend to pay by check.

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Additional Instructions/Comments: Amy, here is a copy
of our latest response, including
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In the meantime, if you have any
questions do not hesitate to call
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Thanks, James

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1638
Examiner : Anne R. Kubelik
Serial No. : 09/807,723
Filed : April 18, 2001
Inventors : Henry Daniell
Title : GENETIC ENGINEERING OF
: PLANT CELLS TO PROVIDE
: ENHANCED EXPRESSION OF
: MULTIPLE FOREIGN GENES
: IN TRANSGENIC PLASTIDS
: UTILITIZING A SINGLE
: TRANSFORMATION EVENT



35811

PATENT TRADEMARK OFFICE

Docket: 1464-PCT-US-00

Confirmation No.: 4031

Dated: July 7, 2003

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Certificate of Mailing Under 37 CFR 1.8

For
Postcard
\$465.00 Check
Claim of Extension of Time for Response, in duplicate
Amendment Transmittal, in duplicate
Amendment
Copy of Revised Interim Written Description Guidelines Training Materials
Copy of COVER of Nature Biotechnology
Copy of Ruiz et al., Plant Physiology, July 2003
Copy of article by Mayfield et al (2003)
Substitute Figs. 1-18B
Declaration of Henry Daniell with Exhibit A

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on the date appearing below.

Name of Applicant, Assignee, Applicant's Attorney
or Registered Representative:

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Customer No. 035811

By: _____

Date: _____

7/7/03

REVISED INTERIM WRITTEN DESCRIPTION GUIDELINES
TRAINING MATERIALS

Contents

Synopsis	4
Decision Trees	
Written Description Amended or New Claims or Claims	
Asserting the Benefit of an Earlier Filing Date	6
Original Claims	7
Example 1: Amended claims	10
Example 2: 35 USC 120 Priority	13
Example 2A: Essential element missing	
from original claim	15
Example 2B: A preferred element missing from original claim	17
Example 3: New claims	19
Example 4: Original claim	22
Example 5: Flow Diagrams	24
Example 6: Genes	27

Example 7: EST	30
Example 8: DNA Fragment Encoding a Full length Open Reading Frame (ORF)	33
Example 9: Hybridization	35
Example 10: Process Claim	38
Example 11: Allelic Variant	41
Example 12: Bioinformatics	47
Example 13: Protein Variant ...	50
Example 14: Product by Function	53
Example 15: Antisense	56
Example 16: Antibodies	59
Example 17: Genus-species with widely varying species.....	61
Example 18: Process claim where the novelty is in the method steps	65

Example 18: Process claim where the novelty is in the method steps.

Specification: The specification teaches a method for producing proteins using mitochondria from the fungus *Neurospora crassa*. In the method, mitochondria are isolated from this fungus and transformed with a mitochondrial expression vector which comprises a nucleic acid encoding a protein of interest. The protein is subsequently expressed, the mitochondria is lysed, and the protein is isolated. The specification exemplifies the expression of β -galactosidase using the claimed method using a cytochrome oxidase promoter.

Claim:

1. A method of producing a protein of interest comprising;
 obtaining *Neurospora crassa* mitochondria,
 transforming said mitochondria with a expression vector comprising a nucleic acid that encodes said protein of interest,
 expressing said protein in said mitochondria, and
 recovering said protein of interest.

Analysis:

A review of the specification reveals that *Neurospora crassa* mitochondrial gene expression is essential to the function/operation of the claimed invention. A particular nucleic acid is not essential to the claimed invention.

A search of the prior art reveals that the claimed method of expression in *Neurospora crassa* is novel and unobvious.

The claim is drawn to a genus, i.e., any of a variety of methods that can be used for expressing protein in the mitochondria.

There is actual reduction to practice of a single embodiment, i.e., the expression of β -galactosidase.

The art indicates that there is no substantial variation within the genus because there are a limited number of ways to practice the process steps of the claimed invention.

The single embodiment is representative of the genus based on the disclosure of *Neurospora crassa* mitochondria as a gene expression system, considered along with the level of skill and knowledge in the gene expression art. One of skill in the art would recognize that applicant was in possession of all of the various expression methods necessary to practice the claimed invention.

Conclusion:

The claimed invention is adequately described.